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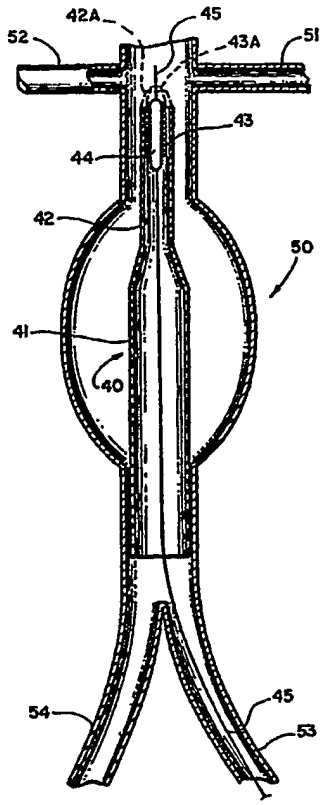
(57) Abstract

An expandable blood vessel graft (40) facilitates the rapid and secure insertion of the graft in a blood vessel (50). The graft includes a first radially pre-expanded portion (41) and a second portion (42). The first portion (41) is connected to the second portion (42). The second portion has a diameter less than the diameter of the first pre-expanded portion. A system for use in a blood vessel, including the above mentioned graft and an expansion element (44), a method for inserting such a graft into a blood vessel, and a process for forming such a graft are also described.



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EXPANDABLE ENDOVASCULAR GRAFT AND METHOD FOR DEPLOYING THE SAME

Background of the Invention

This invention relates to grafts. More particularly, the invention relates to grafts for the blood vessels of animals. In a further respect, the invention relates to expandable blood vessel grafts which facilitate the rapid and secure insertion of the grafts in the blood vessels. In another respect, the invention relates to expandable blood vessel grafts which can be inserted at the bifurcation of a blood vessel.

The use of grafts in the blood vessels of human beings and other animals is well known in the art. However, several disadvantages are associated with prior art grafts. First, the time required to insert a graft can be substantial, particularly when an expandable graft is utilized which requires that an angioplasty balloon be inflated at several positions along the length of the graft in order to properly expand the graft. Second, it is difficult to insert grafts near a bifurcation of a blood vessel, for example, the aortic arterial bifurcation.

Accordingly, it would be highly desirable to provide an improved blood vessel graft which would facilitate the rapid deployment of the graft in a blood vessel and which would facilitate the use of the graft at the bifurcation of a blood vessel.

Summary of the Invention

Therefore, it is a principal object of the invention to provide an improved graft.

A further object of the invention is to provide an improved expandable blood vessel graft which facilitates the deployment of the graft in a blood vessel when the

graft requires expansion at several points along the length of the graft.

Another object of the invention is to provide an improved blood vessel graft and method for inserting the graft at the bifurcation of a blood vessel.

Briefly, in accordance with the invention, I provide a graft for carrying blood. The graft includes a first portion having a diameter, and a second portion connected to said first portion and having a diameter less than the diameter of said first expanded portion. The second portion is expandable with a balloon after the first and second portions are inserted in a blood vessel in the body of an animal.

In another embodiment of the invention, I provide a graft for carrying blood. The graft includes a first portion having a diameter, and a second portion connected to said first portion and having an original diameter. The second portion is expandable with a balloon to a diameter greater than the original diameter after the second portion is inserted in a blood vessel in the body of an animal.

In a further embodiment of the invention, I provide a method for inserting in the body of an animal a graft for carrying blood. The method includes the steps of: providing a graft including a first potion having a diameter, and a second portion connected to the first portion and having a diameter less than the diameter of the first portion, the second portion being expandable with a balloon after the second portion is inserted in a blood vessel in the body of an animal; inserting the second portion in the blood vessel of an animal; and expanding the second portion with a balloon.

In still another embodiment of the invention, I provide a method for inserting in a human being a graft which extends into the aortic blood vessel bifurcation.

The method includes the step of providing a graft. The graft includes: a center portion having a pair of ends and a diameter; a first expandable portion connected to one end of the center portion; a first expandable leg connected to the other end of the center portion; and a second expandable leg connected to the other end of said center portion. A portion of one end of a first length of suture is inserted through one side of the groin of the patient, through one iliac artery, through the other iliac artery, and out the other side of the groin of the patient such that the other end of said suture extends out through said one side of the groin. A portion of the suture extending out the other side of the groin of the patient is attached to the second expandable leg of the graft. A second length of suture is attached to the first expandable leg. The graft is inserted into the aorta through the other side of the groin such that the first and second expandable legs move through the aorta toward the patient's heart and past the junction of iliac arteries. The first and second lengths of the suture are gently drawn in a direction out from the patient's body to move the graft away from the patient's heart such that the first and second expandable legs are each pulled down into one of the iliac arteries. The first expandable portion of the graft is expanded with a stent to secure the graft in place in the aorta.

In one aspect, the invention features a graft for use in a blood vessel, said graft including: (a) a first, large diameter portion having a diameter corresponding substantially to the inner diameter of the vessel, the large diameter portion being formed of a foldable synthetic material such that the portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site; and (b) a

second, small diameter portion connected to the large diameter portion and having a substantially uniform diameter that is less than the diameter of the large diameter portion and the diameter of the vessel to facilitate insertion into the vessel, the small diameter portion being formed of a synthetic material such that the portion can be radially expanded to the vessel wall diameter after insertion in a blood vessel.

In another aspect, the invention features a system for use in a blood vessel, said system including a graft and an expansion element. The graft includes (a) a first, large diameter portion having a diameter corresponding substantially to the diameter of the vessel and a length substantially greater than the expansion element, the large diameter portion being formed of foldable synthetic material such that the large diameter portion can be reduced to smaller profile to facilitate insertion into the vessel and can be extended substantially to the diameter of the vessel once positioned at a desired site; and (b) a second, small diameter portion connected to the large diameter portion and having a diameter that is less than the diameter of the large diameter portion and the vessel diameter to facilitate insertion into the vessel; the small diameter portion being formed of an expandable synthetic material such that the small diameter portion can be radially expanded with the expansion element to a diameter greater than the original diameter after insertion in the vessel.

In yet another aspect, the invention features a method for inserting a graft in a vessel. The method includes the steps of: (a) providing a system as described above, including a graft and an expansion element; (b) positioning the graft in a manner that the small diameter portion is located about the expandable element and the large diameter portion is reduced to a

profile smaller than the vessel diameter; (c) inserting the graft and the expansion element in the blood vessel and locating the graft at a desired site; (d) radially expanding the small diameter portion with the expansion element; and (e) collapsing the expansion element, and removing the expansion element from the vessel while leaving the graft in the vessel.

Embodiments may include one or more of the following features. The graft is preferably a continuous tube-form of a single synthetic material. The graft is preferably formed of PTFE. The small diameter portion of the graft preferably has a shorter length than the large diameter portion. The large diameter portion of the graft preferably has a length sufficient to span a diseased area while the end portion is selected to engage a healthy portion of vessel adjacent the diseased portion. An expandable metallic stent is preferably attached to the synthetic material and preferably extends only in the small diameter portion. The small diameter portion of the graft is preferably at an end of the graft. First and second small diameter portions are preferably arranged with the large diameter portion therebetween. The graft preferably includes a small diameter portion at only one end. A sheath is preferably included for delivery of the graft into the vessel. The expansion element is preferably an inflatable balloon. The balloon is preferably an angioplasty balloon. The graft and expansion element are preferably delivered over a guidewire. The graft and expansion element are preferably delivered through a sheath.

In a further aspect, the invention features a graft for use in a blood vessel. The graft comprises: a continuous tube-form of a single synthetic material including: (a) a first, large diameter portion having a diameter corresponding substantially to the inner

diameter of the vessel, the synthetic material in the large diameter portion being foldable such that the portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site; and (b) a second, small diameter portion connected to the large diameter portion and forming an end of the graft, the small diameter portion having a substantially uniform diameter that is less than the diameter of the large diameter portion and the diameter of the vessel to facilitate insertion into the vessel, the small diameter portion being formed of the synthetic material and including an expandable metal stent extending only in the small diameter portion such that the portion can be being radially expanded to the vessel wall diameter after insertion in a blood vessel.

Embodiments may include one or more of the following features. The small diameter portion of the graft preferably has a shorter length than the large diameter portion. First and second small diameter portions are preferably arranged with the large diameter portion of the graft therebetween. The graft preferably includes a small diameter portion at only one end. The graft is preferably formed of PTFE.

In another aspect, the invention features a method for forming a graft for use in a blood vessel. The method comprises the steps of: providing a continuous tube-form of a single synthetic material, the tube form having a diameter smaller than the diameter of the vessel; inserting an expandable member into the tube form, the expansion element having a length that is shorter than the length of the tube-form; expanding the expansion element to radially expand the synthetic material to form a first, large diameter portion having a diameter corresponding substantially to the inner

diameter of the vessel; the synthetic material in the large diameter portion being foldable such that the portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site, and to form a second, small diameter portion connected to the large diameter portion and forming an end of the graft, the small diameter portion having a substantially uniform diameter that is less than the diameter of the large diameter portion and the diameter of the vessel to facilitate insertion into the vessel, the small diameter portion being formed of the synthetic material such that the portion can be radially expanded to the vessel wall diameter after insertion in the blood vessel.

The invention also features a graft for use in a blood vessel formed by the above-mentioned process.

These and other, further and more specific, objects and advantages of the invention will be apparent to those skilled in the art from the following detailed description thereof, taken in conjunction with the drawings and the claims.

Brief Description of the Drawings

Fig. 1 is a side section view illustrating a blood vessel graft constructed in accordance with the principles of the invention.

Fig. 2 is a side section view illustrating another embodiment of the blood vessel graft of the invention.

Fig. 3 is a side section view illustrating still another embodiment of the blood vessel graft of the invention.

Fig. 4 is a side section view illustrating the graft of Fig. 3 provided with a stent and with an angioplasty balloon for securing the graft in position in a blood vessel.

Fig. 5 is a side section view illustrating an aortic aneurysm with the graft of Figs. 3 and 4 inserted therein.

Fig. 6 is a side section view illustrating the aneurysm and graft of Fig. 5 after an angioplasty balloon is used to expand a stent and secure the graft in the aorta.

Fig. 7 is a side section view illustrating the aneurysm and graft of Fig. 6 after the proximal portion of the graft has been completely expanded.

Fig. 8 is a side section view illustrating an aortic aneurysm after a suture look has been coursed through the iliac arteries.

Fig. 9 is a side section view illustrating the aortic aneurysm of Fig. 8 after a split-leg graft has been inserted above the bifurcation of the aorta.

Fig. 10 is a side section view illustrating the aneurysm and graft of Fig. 9 after an angioplasty balloon is used to expand a stent in the aorta above the aneurysm to secure the graft in place.

Fig. 11 is a side section view of the aneurysm and graft of Fig. 10 illustrating the insertion of a stent on one of the distal split legs of the graft to secure the graft in an iliac artery.

Description of the Preferred Embodiments

We turn now to the drawings, which depict the presently preferred embodiments of the invention for the purpose of illustrating the practice thereof, and not by way of limitation of the scope of the invention, and in which like reference characters refer to corresponding elements throughout the several views. Fig. 1 illustrates a graft 20 constructed in accordance with the invention. In the graft 20 of Fig. 2, the diameter of center portion 21 is greater than the diameter of the proximal portion 22 and distal portion 23. The graft 20

is preferably made by taking a length of material like thin, pliable, expandable polytetrafluoroethylene (PTFE) tubing and expanding an intermediate section of the tubing to form center portion 21 while not expanding the proximal portion 22 and distal portion 23. Fabricating graft 20 from a thin, pliable, readily foldable material is preferred because one primary application of the graft requires that the graft can be folded into a small configuration so the graft can be inserted into a blood vessel in a sheath or sleeve which slides along a guide wire inserted in the blood vessel.

If desired, the central portion 21 can be made from a material different than the material used to make the proximal portion 22 and/or distal portion 23. Portion 22 can be made of a material different from that of portions 21 and/or 23. Central portion 21 also need not be expandable and can, for example, be fabricated from dacron, nylon or some other synthetic material which has a diameter larger than the diameter of the proximal and distal portions 22, 23 and which is not expandable. Central portion 21 can be sutured or otherwise attached to the proximal portion 22 and/or distal portion 23. When, however, graft 20 is inserted in the body, the diameter of portion 21 is larger than the diameter of proximal and distal portions 22 and 23, and the diameter of portion 21 normally need not be increased after graft 20 is inserted in the body. Not having to increase the diameter of portion 21 after graft 20 is inserted in the body is an important advantage of the invention. After graft 20 is inserted in the body, the diameter of center portion 21 can, if desired, be increased with a balloon is portion 21 is made from an expandable material. Regardless of the materials utilized to fabricate graft 20, it is preferred, that the graft can be folded or compressed and reduced to a size which facilitates

insertion of the graft through a sheath into the desired blood vessel in the body.

As used herein, the term diameter refers to the outside diameter of the material used in the grafts of the invention. The grafts described herein consist of hollow cylindrical or substantially cylindrical portions. For example, central portion 21, proximal portion 22, and distal portion 23 are cylindrical hollow members.

The graft 30 of Fig. 2 is, like graft 20, preferably made by taking a length of thin, pliable, foldable, hollow PTFE tubing and expanding an intermediate section to form center portion 31. Center portion 31 has a diameter that is greater than the proximal portion 32 and distal portion 33. The diameter of proximal portion 32 equals that of the original, unexpanded PTFE tubing, i.e., portion 32 comprises unexpanded PTFE tubing. The distal portion 33 is formed by expanding the PTFE tubing to a diameter which is greater than the diameter of portion 32 and less than the diameter of central portion 31. The diameter of distal portion 34 attached to opening 36 is also greater than the diameter of proximal portion 32 and is less than the diameter of center portion 31. Portion 34 is formed by expanding or pre-dilating hollow PTFE tubing. As discussed in connection with graft 20, portion 31 need not be made of an expandable material, and can be made from a material different than that of portions 32 and 33.

The graft 40 of Fig. 3 is, like grafts 20 and 30, preferably made by taking a length of thin, pliable, foldable, hollow PTFE tubing and expanding an end section of the tubing to form portion 41. Portion 41 has a diameter that is greater than the proximal portion 42. As discussed in connection with graft 20, portion 41 need

not be made of an expandable material, and can be made from a material different that of portion 42.

The following examples are presented by way of illustration, and not limitation, of the practice of the invention.

EXAMPLE 1

The graft 20 of Fig. 1 is made by taking a length of two mm diameter PTFE tubing and expanding the center portion 21 to eight mm by introducing a balloon inside portion 21 and expanding the balloon with pressurized water. The diameter of proximal portion 22 is two mm. The diameter of the pre-dilated center portion 21 in Fig. 1 is, as noted, eight mm. Radiopaque marker 84 is attached to proximal portion 22. Radiopaque marker 85 is attached to distal portion 23. Stents 24 and 27 are inserted in proximal portion 22 and distal portion 23, respectively. A balloon 25 is introduced in stent 24 and is expanded to about one atmosphere pressure to secure the balloon 25 in place inside stent 24 without causing stent 24 to expand. The balloon is carried on shaft 26. The graft 20--stents 24, 27--balloon 25--shaft 26 of Fig. 1 are tightly folded inside a sheath and inserted in a selected blood vessel about eight mm in diameter. Once the graft 20 is at the desired position in the blood vessel, balloon 25 is used to expand stent 24 and proximal portion 22 to about eight mm. After stent 24 is expanded, balloon 25 is deflated and moved to a position inside stent 27 and distal portion 23 to about eight mm.

EXAMPLE 2

The graft 40 of Fig. 3 is made by taking a length of five mm diameter expandable PTFE tubing and pre-expanding one end of the tubing to form the distal portion 41. Portion 41 has a diameter of 18 mm. The proximal portion 42 is not pre-expanded and has a diameter of five mm. A radiopaque marker 82 is affixed

to the proximal portion 42. Another radiopaque marker 83 is affixed to the distal portion 41. The distal portion 41 is long enough to span an aneurysm in the procedure described below in this Example 2. A balloon expandable aortic stent 43 is inserted in proximal end 42.

A four cm long collapsed or folded angioplasty balloon 44 is inserted in stent 43, in the manner shown in Fig. 4, and inflated to two to three atmospheres to secure the balloon in stent 43 and proximal portion 42. Balloon 44 is carried on a guide wire 45. If the balloon is inflated standing alone outside of stent 43, it has an initial diameter of twenty cm after the balloon is filled sufficiently (to a pressure of about one atmosphere) to remove the folds from the balloon and assume a smooth accurate configuration. As the pressure of water in the balloon is increased, the diameter of the balloon increases to its maximum labeled diameter.

In Fig. 4, the stent 43 is mounted in balloon 40 so that one end of stent 43 extends two mm outside the left-hand end of proximal portion 42. If desired, stent 43 can be attached to proximal portion 42 with a single prolene suture or by any other desired means, including a staple.

After the balloon is inflated to two to three atmospheres in the configuration shown in Fig. 4, an eighteen Fr. (French) sheath is used to introduce the graft 40--stent 43--balloon 44 configuration through the common femoral artery percutaneously and to the level of the neck of the aneurysm 50, below the renal arteries 51 and 52, as shown in Fig. 5. The sheath is retracted or pulled along guide wire 45 to a position in the iliac artery 53. In Fig. 5, the end of proximal portion 42 is positioned in the proximal aneurysmal neck of the blood vessel. The end of distal portion 41 is positioned above the aortoiliac bifurcation.

In Fig. 5, the balloon 44 is expanded to expand stent 43 to force proximal portion 42 against the aneurysmal neck of the blood vessel and fix the graft 40 in place. Stent 43 and portion 42 are expanded to a diameter of about eighteen mm. Because of the high blood flow pressure through the aorta, a balloon is used to occlude the aorta from above, while balloon 44 is expanded. Or, a steady pressure is applied to shaft 45 to hold balloon 44 in place during its inflation.

If desired, proximal portion 42 can include a tapered tip 42A and stent 43 can include a tapered tip 43A, which are not expanded when balloon 44 is expanded in Fig. 5. In this case, after stent 43 and proximal portion 42 are expanded to the configuration shown in Fig. 6, then balloon 44 is deflated and moved upwardly in Fig. 5 into tapered tip 42A, where balloon 44 is again expanded to expand tip 43A and tip 42A to a diameter of about 18 mm.

In Fig. 6, balloon 44 has been deflated and moved downwardly to a new position to expand the remaining unexpanded portion of proximal portion 43. After balloon 44 is in the position shown in Fig. 6, it is expanded to expand the constricted section of proximal portion 43 to about eighteen mm. The proximal portion 43 can be expanded to about eighteen mm because the balloon operator knows what balloon inflation pressure is required to expand the proximal portion 43 from five mm to eighteen mm and can view this procedure fluoroscopically.

Once proximal portion 43 is expanded to about eighteen mm along its entire length, balloon 44 is deflated and removed and, as shown in Fig. 7, an aortic stent 55 is deployed in the lower end of graft 40. A balloon 44 is used to expand stent 55 to force the lower end of distal portion 41 against the wall of the blood

vessel. Balloon 44 is then deflated, and balloon 44 and shaft 45 are removed from the patient's body.

EXAMPLE 3

The graft 30 of Fig. 2 is made by taking a length of five mm diameter expandable PTFE tubing and pre-expanding an intermediate portion of the tubing to form the central portion 31. Portion 31 has a diameter of 20 mm. The proximal portion 32 is not pre-expanded and has a diameter of five mm. The first distal portion 33 is made by pre-dilating an end of the five mm tubing to nine mm with a nine mm angioplasty balloon catheter. Opening 36 is formed through graft 30 and the end 35 of a length 34 of pre-expanded PTFE is securely sutured around opening 36. The opening 36 is nine to ten mm wide and opens on the side of the graft. The anastomosis is from end to side. A size 4/0 PTFE, or similar material, continuous suture is used for the anastomosis. Length 34 comprises the second distal portion of the graft 30. Distal portion 34 is formed by pre-dilating a length of five mm diameter PTFE before portion 34 is sutured around opening 36. A radiopaque marker 81 is affixed to the outer end of distal portion 33. Another radiopaque marker 80 is affixed to the outer end of distal portion 34. A third radiopaque marker 86 is affixed to the outer end of proximal portion 32. If the graft 30 is being used to treat an aneurysm, the central portion 31 is long enough to span an aneurysm in the procedure described below in this Example 3. A balloon expandable aortic stent 43 is inserted in proximal end 42.

An aortic balloon expandable stent is inserted in the proximal end 32, followed by a twenty mm angioplasty balloon 65 (assuming the neck of the blood vessel above the aneurysm is about twenty mm in diameter). Balloon 65 is positioned inside stent 66. The wire 64 carrying balloon 65 extends from balloon 65 through center portion

31 and out through distal portion 34. The balloon 65 is inflated to a pressure of one to three atmospheres in order to fix the balloon and stent in graft 30. The one to three atmosphere pressure is less than the pressure needed to expand stent 66 and the proximal portion 32 is marked with a clip. The stent 66 can be secured to portion 32 with one or two single prolene sutures.

A loop 62 of prolene suture is introduced in a nine Fr. sheath 60 through the patient's right groin and is passed through iliac artery 54, through artery 53, through the eighteen Fr. sheath 61, and out through the patient's left groin in the manner illustrated in Fig. 8. The end of loop 62 extending out of the patient's left groin is secured to the end of distal portion 33. Another loop 63 of suture is secured to the end of distal portion 34.

The graft 30--stent 66--balloon 65 is reduced or compressed into sheath 61 for the percutaneous introduction through artery 53 into the aorta of the patient. After graft 30 and sheath 61 are positioned in the aorta, sheath 61 is withdrawn into the iliac artery 53 and graft 30 is positioned in the aorta with distal portions 33 and 34 above the aortic bifurcation as shown in Fig. 9. As would be appreciated by those of skill in the art, radiopaque markers 80, 81, and 86 permit the ready location of the graft 30 in the patient. In Fig. 9, loop 62 extends from distal portion 33 out through the right groin of the patient. Loop 63 extends from distal portion 34 out through the left groin of the patient.

After graft 30 is in the position shown in Fig. 9, loops 62 and 63 are gently pulled to displace graft 30 in the direction of arrow A in Fig. 9 and to move distal portion 33 into artery 54 and distal portion 34 into artery 53 so that graft 30 assumes the general position illustrated in Fig. 10.

After graft 30 is in the general position shown in Fig. 10, balloon 65 is inflated to expand stent 66 and proximal end 32 to secure the graft in the aorta above aneurysm 50. Fig. 10 illustrates stent 66 and proximal portion 32 after balloon 65 has been inflated to expand stent 66, and after balloon 65 has then been deflated and moved downwardly into the remaining unexpanded portion of proximal portion 32. If possible, stent 66, portion 32, and/or balloon 65 can be sized such that after balloon 65 is inflated to expand stent 66, the entire length of portion 32 is expanded. In Fig. 10, portion 32 is expanded to a diameter approximately equal to the diameter of central portion 31.

After portion 32 is expanded and balloon 65 is deflated, the blood flow through the aorta helps to open distal portions 33 and 34.

Balloon 65 and shaft 64 are removed from the patient. Loops 62 and 63 are removed. Stent 72 is inserted in distal portion 34 in the position shown in Fig. 11 and is expanded with balloon 71 on shaft 70 to secure portion 34 in artery 53. A similar stent is inserted in the lower end of distal portion 33 and is expanded to secure portion 33 in artery 54.

The expandable stents shown in Figs. 1, 4 to 7, and 9 to 11 can be positioned inside a graft, outside of the graft, or intermediate layers of graft material when the graft is made from laminate cylindrical members. Many kinds of expandable stents are known in the art and will not be detailed herein. While it is possible that a self expanding stent could be utilized in the practice of the invention, it is presently preferred that balloon expandable stents be utilized to insure that the stents securely anchor a graft to a blood vessel.

Other embodiments are within the scope of the claims.

What is claimed is:

1. A graft for use in a blood vessel, said graft including:

(a) a first, large diameter portion having a diameter corresponding substantially to the inner diameter of said vessel, said large diameter portion being formed of a foldable synthetic material such that said portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site; and

(b) a second, small diameter portion connected to said large diameter portion and having a substantially uniform diameter that is less than the diameter of said large diameter portion and the diameter of said vessel to facilitate insertion into the vessel, said small diameter portion being formed of a synthetic material such that said portion can be radially expanded to the vessel wall diameter after insertion in a blood vessel.

2. A system for use in a blood vessel, said system including:

a graft and an expansion element, said graft including:

(a) a first, large diameter portion having a diameter corresponding substantially to the diameter of said vessel and a length substantially greater than said expansion element, said large diameter portion being formed of foldable synthetic material such that said large diameter portion can be reduced to smaller profile to facilitate insertion into said vessel and can be extended substantially to the diameter of the vessel once positioned at a desired site; and

(b) a second, small diameter portion connected to said large diameter portion and having a diameter that is less than the diameter of said large diameter portion and said vessel diameter to facilitate insertion into the vessel and, said small diameter portion being formed of an expandable synthetic material such that said small diameter portion can be radially expanded with said expansion element to a diameter greater than said original diameter after insertion in said vessel.

3. A method for inserting a graft in a vessel, said method including the steps of:

(a) providing a system as described in claim 2;

(b) positioning said graft in a manner that said small diameter portion is located about said expandable element and said large diameter portion is reduced to a profile smaller than said vessel diameter;

(c) inserting said graft and said expansion element in the blood vessel and locating said graft at a desired site;

(d) radially expanding said small diameter portion with said expansion element; and

(e) collapsing said expansion element, and removing said expansion element from the vessel while leaving said graft in said vessel.

4. The graft of claim 1 or the system of claim 2 wherein said graft is graft is a continuous tube-form of a single synthetic material.

5. The graft or the system of claim 4 where said graft is formed of PTFE.

6. The graft of claim 1 or the system of claim 2 wherein said small diameter portion has a shorter length than said large diameter portion.

7. The graft or the system of claim 6 wherein said large diameter portion has a length sufficient to span a diseased area while said end portion is selected to engage a healthy portion of vessel adjacent said diseased portion.

8. The graft of claim 1 or the system of claim 2 including an expandable metallic stent attached to said synthetic material and extending only in said small diameter portion.

9. The graft of claim 1 or the system of claim 2 wherein said small diameter portion is at an end of said graft.

10. The graft of the system of claim 8 including first and second small diameter portions arranged with said large diameter portion therebetween.

11. The graft or the system of claim 8 where said graft includes a small diameter portion at only one end.

12. The system of claim 2 further including a sheath for delivery of said graft into said vessel.

13. The system of claim 2 wherein said expansion element is an inflatable balloon.

14. The system of claim 13 wherein said balloon is an angioplasty balloon.

15. The method of claim 3 comprising delivering said graft and expansion element over a guidewire.

16. The method of claim 3 comprising delivering said graft and expansion element through a sheath.

17. The method of claim 3 wherein said expansion element is an inflatable balloon.

18. A graft for use in a blood vessel, said graft comprising:

a continuous tube-form of a single synthetic material including:

(a) a first, large diameter portion having a diameter corresponding substantially to the inner diameter of said vessel, said synthetic material in said large diameter portion being foldable such that said portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site; and

(b) a second, small diameter portion connected to said large diameter portion and forming an end of said graft, said small diameter portion having a substantially uniform diameter that is less than the diameter of said large diameter portion and the diameter of said vessel to facilitate insertion into the vessel, said small diameter portion being formed of said synthetic material and including an expandable metal stent extending only in said small diameter portion such that said portion can be being radially expanded to the vessel wall diameter after insertion in a blood vessel.

19. The graft of claim 18 wherein said small diameter portion has a shorter length than said large diameter portion.

20. The graft of the system of claim 19 including first and second small diameter portions arranged with said large diameter portion therebetween.

21. The graft or the system of claim 19 where said graft includes a small diameter portion at only one end.

22. The graft of any one of claims 18 to 21 where said graft is formed of PTFE.

23. A method for forming a graft for use in a blood vessel, said method comprising:

providing a continuous tube-form of a single synthetic material, said tube form having a diameter smaller than the diameter of said vessel;

inserting an expandable member into said tube form, said expansion element having a length that is shorter than the length of said tube-form;

expanding said expansion element to radially expand said synthetic material to form a first, large diameter portion having a diameter corresponding substantially to the inner diameter of said vessel, said synthetic material in said large diameter portion being foldable such that said portion can be reduced to smaller profile to facilitate insertion into the vessel and be extended substantially to the diameter of the vessel once positioned at a desired site, and to form a second, small diameter portion connected to said large diameter portion and forming an end of said graft, said small diameter portion having a substantially uniform diameter that is

less than the diameter of said large diameter portion and the diameter of said vessel to facilitate insertion into the vessel, said small diameter portion being formed of said synthetic material such that said portion can be radially expanded to the vessel wall diameter after insertion in said blood vessel.

24. A graft for use in a blood vessel formed by the process in claim 23.

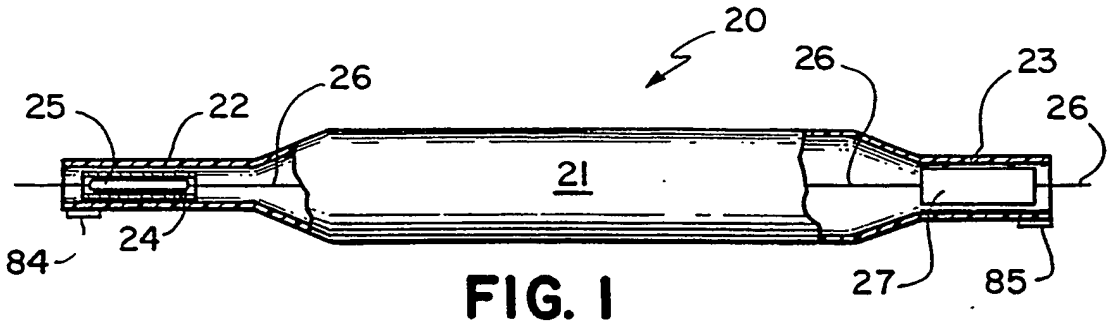

FIG. 1

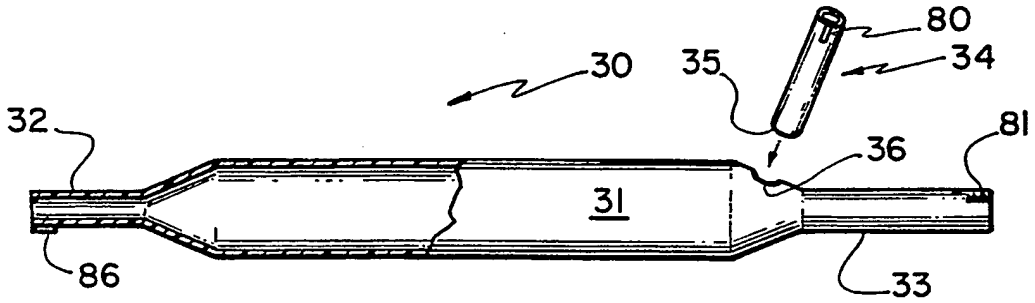

FIG. 2

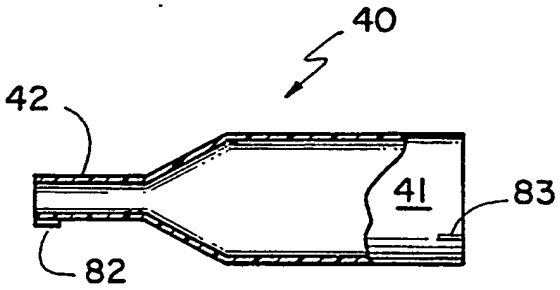

FIG. 3

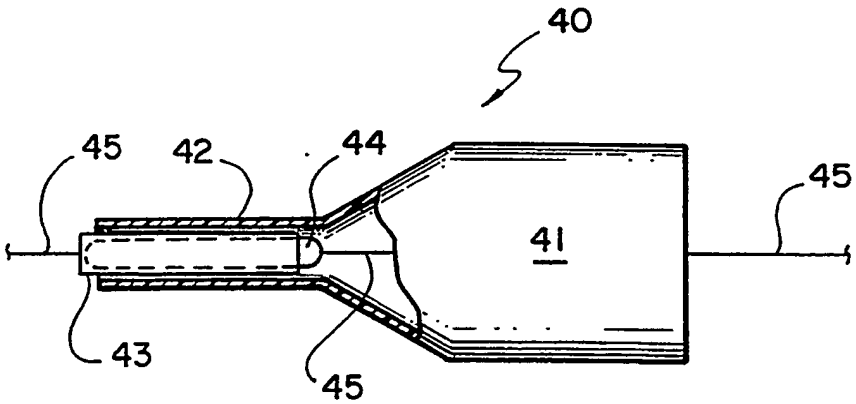

FIG. 4

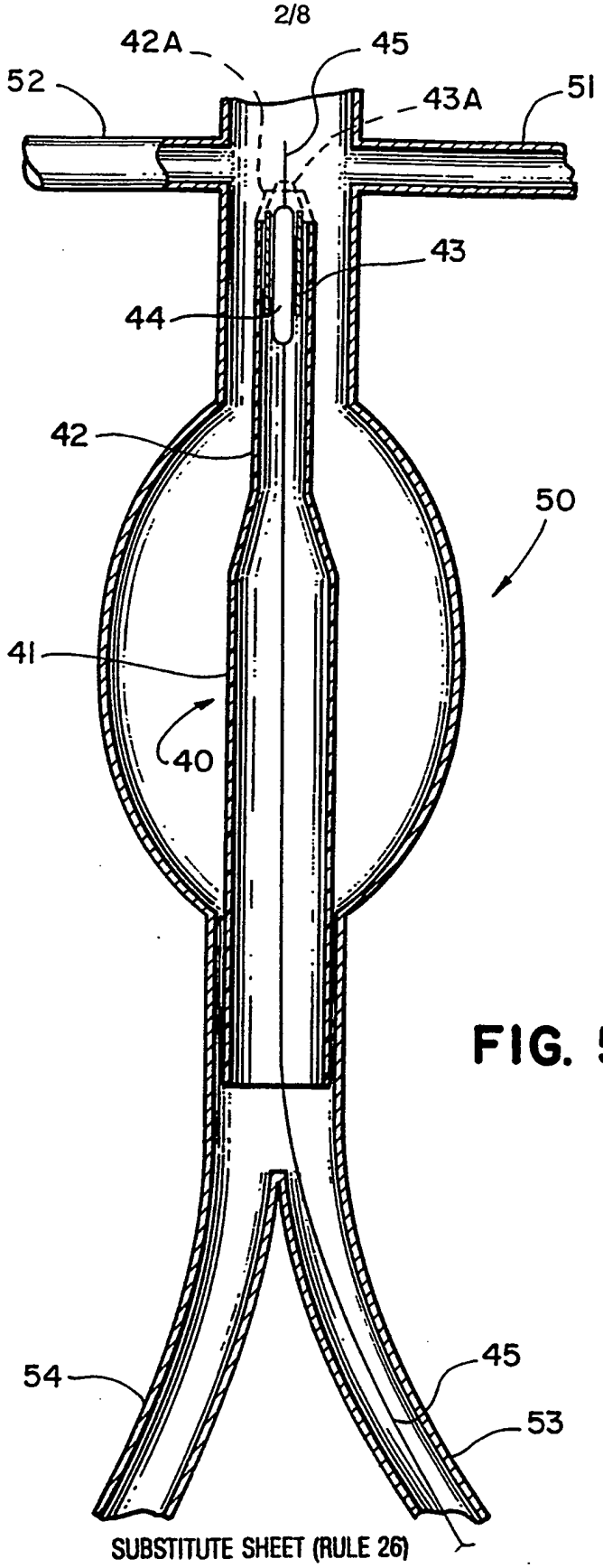

FIG. 5

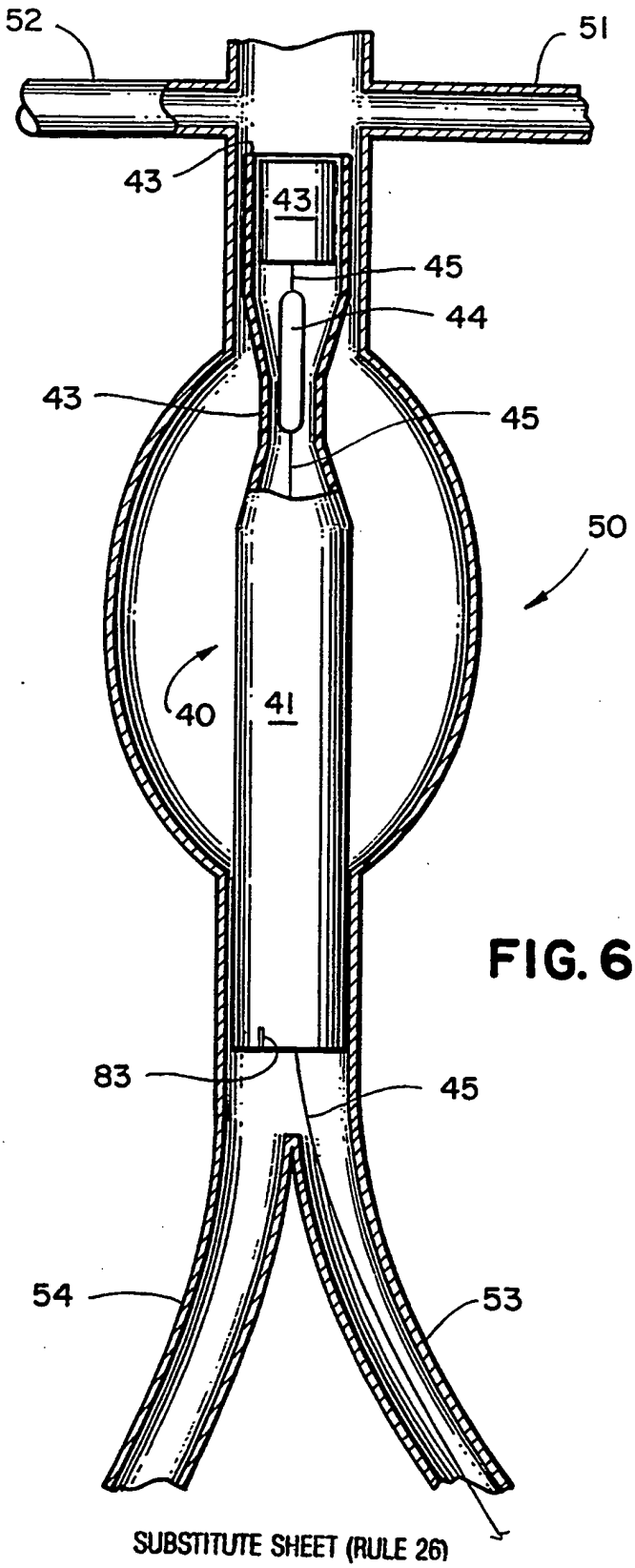

FIG. 6

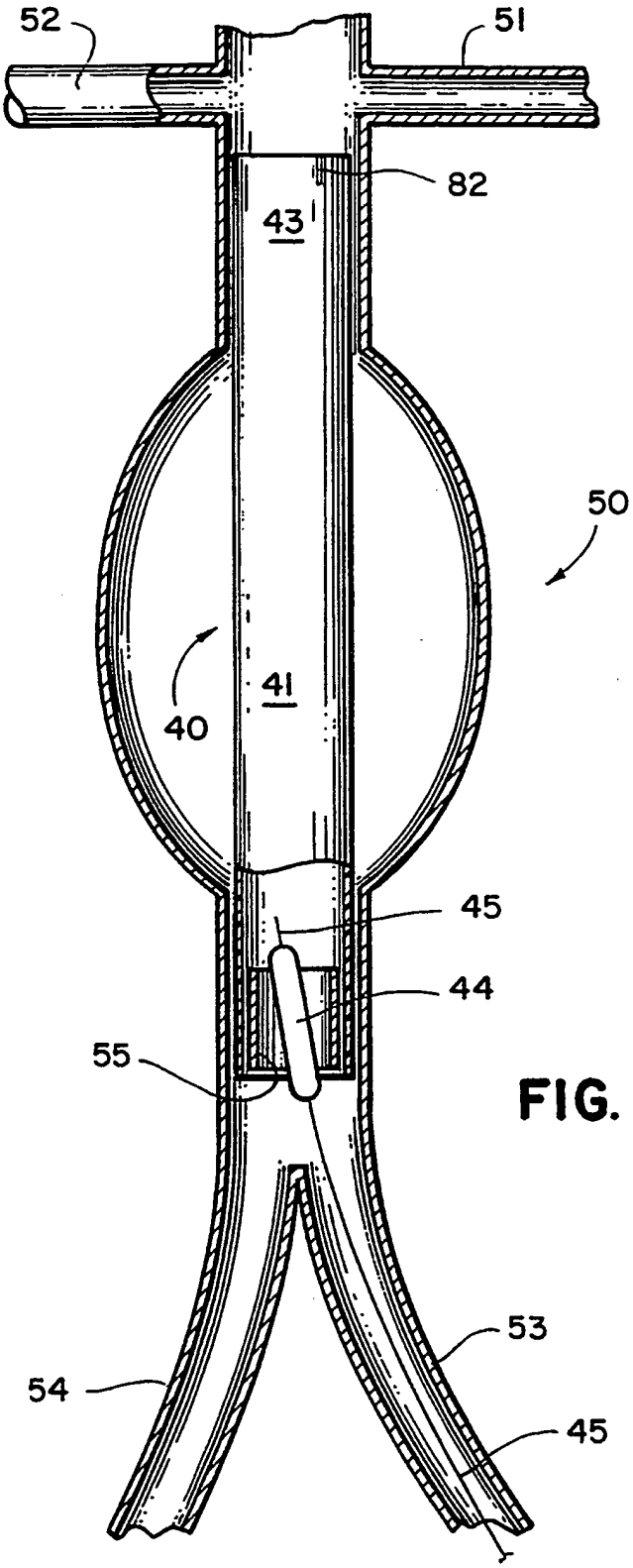

FIG. 7

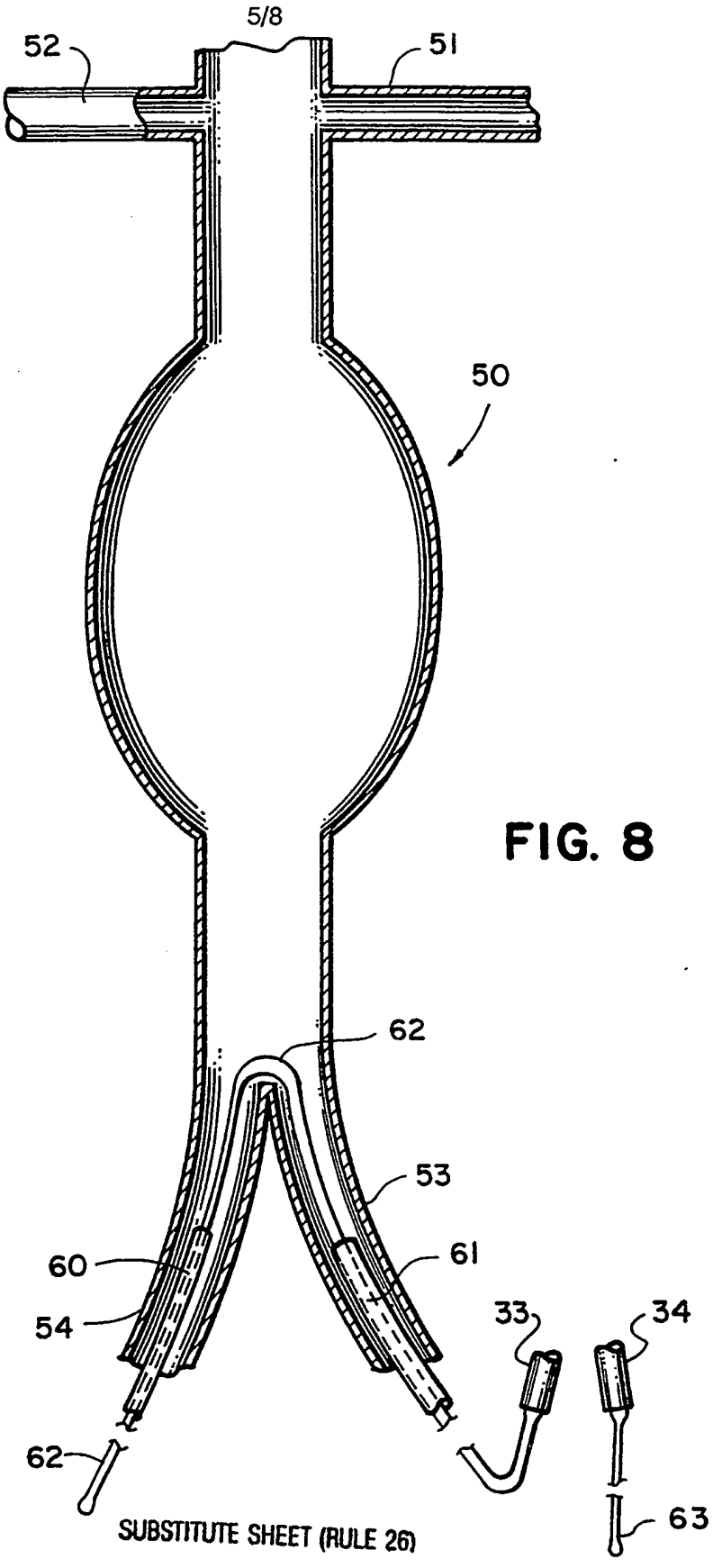

FIG. 8

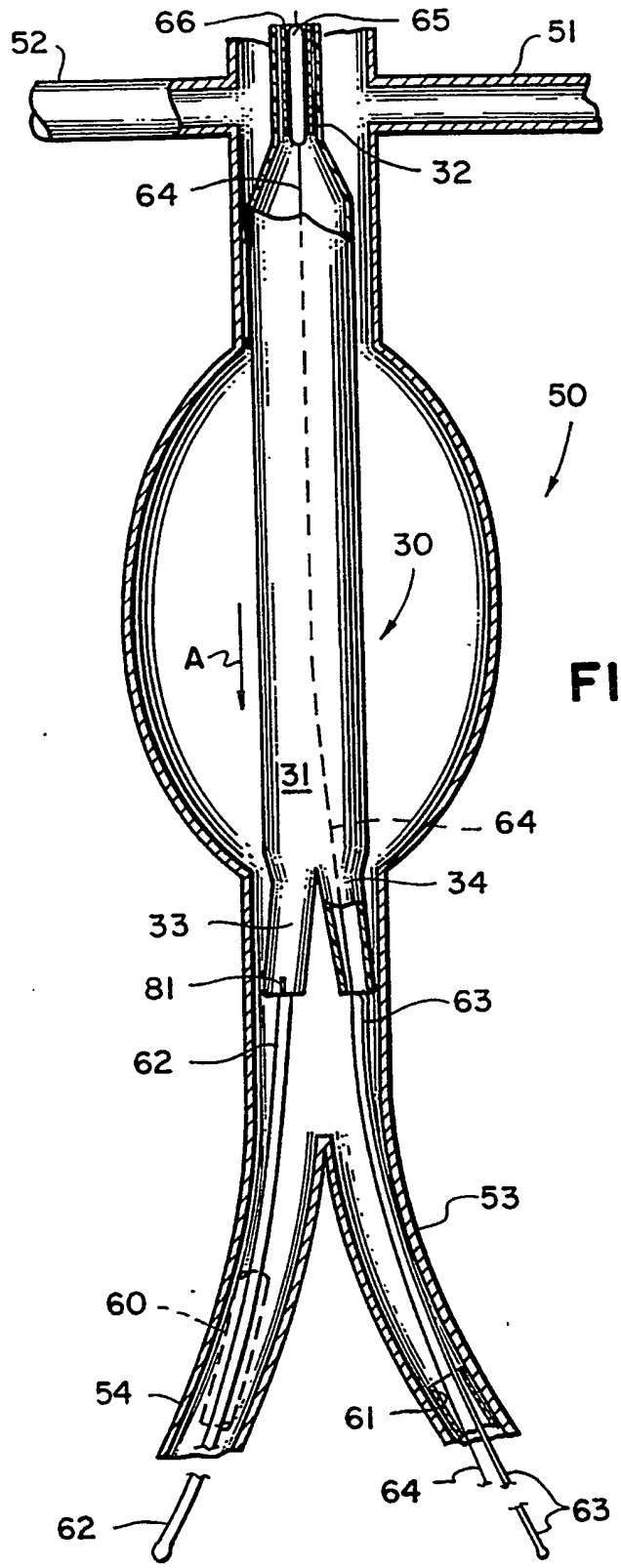

FIG. 9

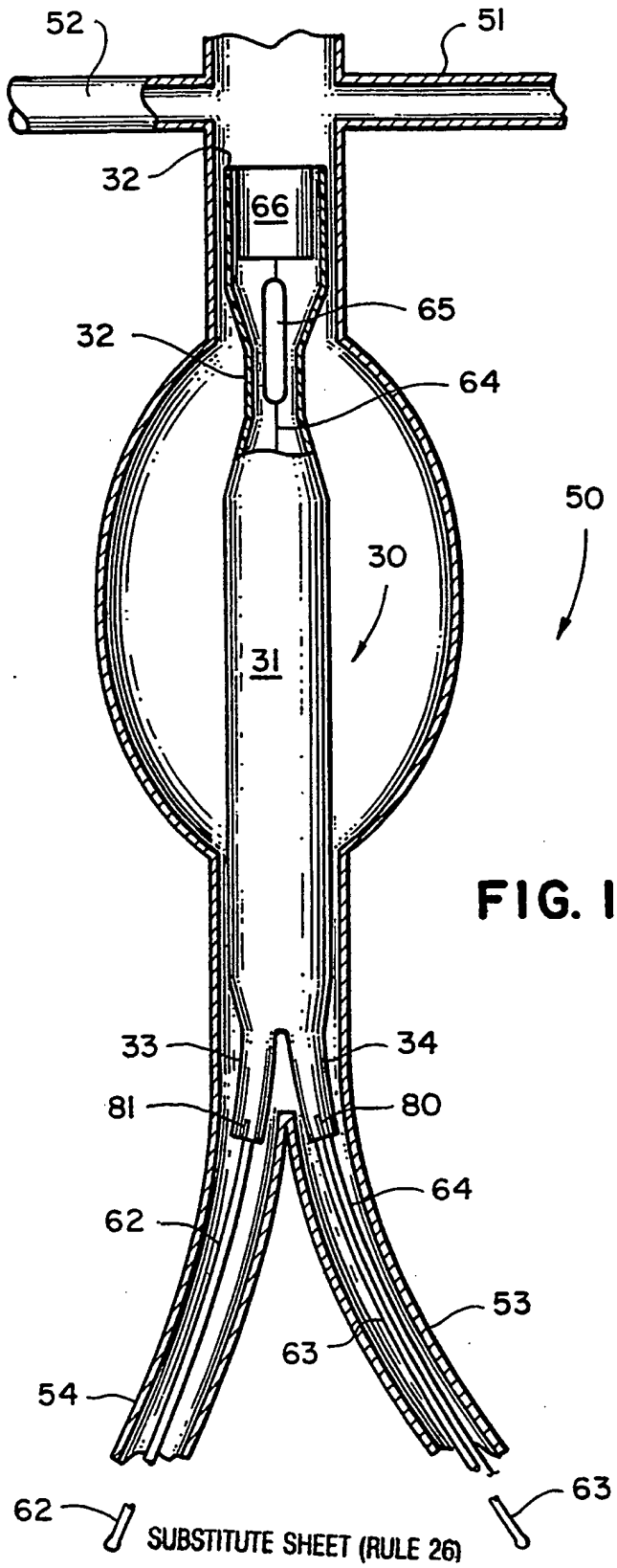

FIG. 10

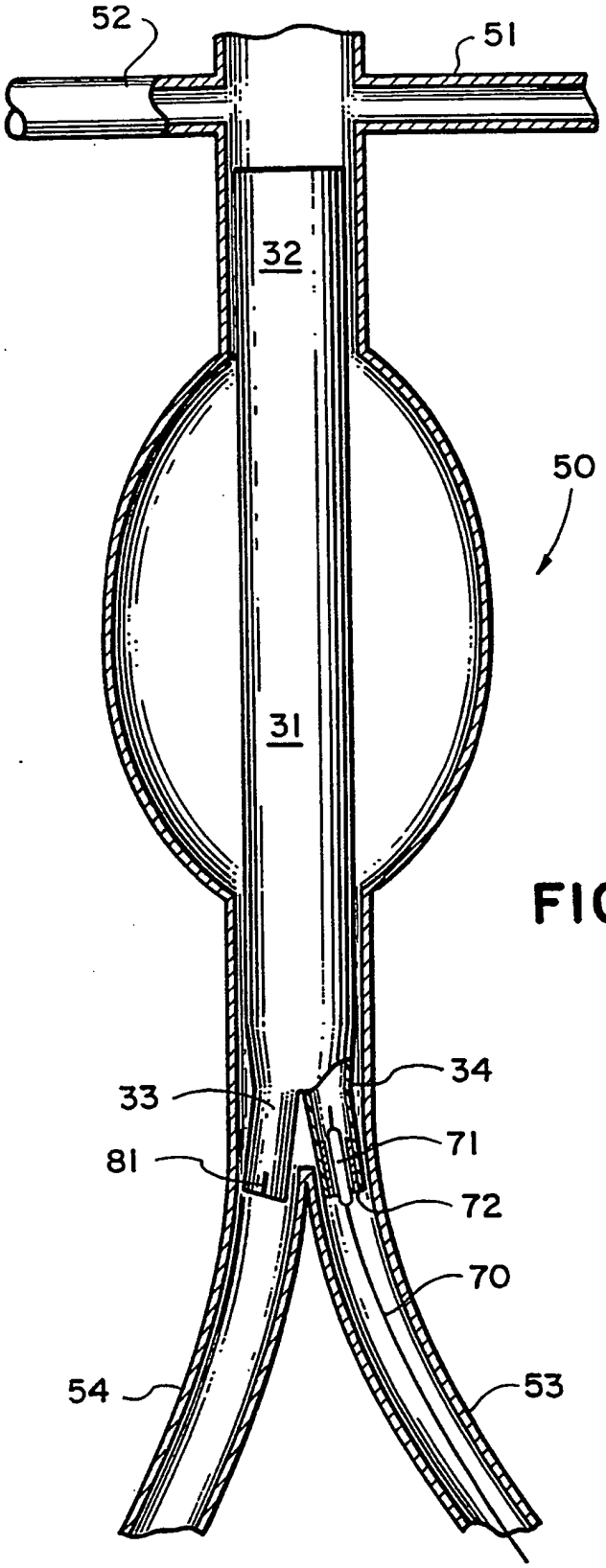

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/07258

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06; A61M 29/02
US CL :606/194, 195; 623/1, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/29-31; 604/7, 8, 175; 606/191-198; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	US, A, 5,360,443 (BARONE ET AL.) 01 November 1994, see entire document.	1-24
X, E	US, A, 5,425,765 (TIEFENBRUN ET AL.) 20 June 1995, see entire document.	3, 23
A	US, A, 5,316,023 (PALMAZ ET AL.) 31 May 1994, see entire document.	1-24
A	US, A, 4,743,251 (BARRA) 10 May 1988, see entire document.	1, 18
A	US, A, 5,108,424 (HOFFMAN, JR. ET AL.) 28 April 1992, see entire document.	1, 18
A	US, A, 5,078,726 (KREAMER) 07 January 1992, see entire document.	1-24

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
21 JULY 1995	10 AUG 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DENNIS RUHL Telephone No. (703) 308-2262

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/07258

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,258,020 (FROIX) 02 November 1993. See entire document.	1-24